UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Note to Reader
September 9, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply, EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, if unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues

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available in the information in this docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack Housenger, Acting Director
Special Review and Reregistration
Division

6/24/98

MEMORANDUM

SUBJECT: Sulfotepp (PC 079501). Preliminary Risk Assessment and Recommendations for Additional Action.

FROM: R. Griffin and J. Becker
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Submitted sulfotepp toxicological and exposure data are *inadequate* for risk assessment. This memo provides a *preliminary* risk assessment for application and post-application worker exposure to sulfotepp, and makes recommendations for additional data and label amendments.

The following inhalation risk assessment is based on an endpoint/dose obtained from a route specific study obtained from a *secondary* data source (journal article, original data not reviewed by the Agency). This study was cited by ACGIH as the data source for setting the TLV/PEL.

The following intermediate-term dermal risk assessment is based the endpoint/dose established in a non route-specific (oral) subchronic toxicity study, classified as acceptable by the Agency for regulatory purposes. However, the dose used for short-term dermal risk assessment is an extrapolation based on the results seen in similar organophosphate pesticides (ethyl parathion), and the study did not establish a NOEL for females.

Application/post-application inhalation exposure data is also taken from a secondary data source (journal article, original data not reviewed by the Agency) and a Cal EPA residue study which is not GLP/guideline acceptable. These studies may underestimate actual exposures.

Due to the significant lack of data, sulfotepp has not been reviewed by the HED Hazard Identification Committee. This Committee evaluates toxicological data for adequacy, establishes endpoints/doses for risk assessment, and most significantly for sulfotepp, establishes Margin of Exposure requirements for risk assessment and regulatory purposes (data gaps as seen in the sulfotepp database typically increase MOE requirements to significantly higher levels than the standard 100 used to account for inter/intra-species variability).

At this point, HED can conclude that the risk to workers during the initial application of sulfotepp can be adequately addressed by the use of correct personal protective equipment and procedures. However, at this point, given the toxicological/exposure data gaps, HED cannot conclude that the risk to post-application workers has been adequately defined *or* addressed.

For these reasons, the following risk assessment and recommendations are considered by the Agency to be *preliminary* and are likely to change based on new data, re-review of existing data, and discussions with the registrants (and growers) which HED considers essential for the resolution of all the outstanding issues and concerns.

This document was developed in conjunction and with the concurrence of the Cal EPA - DPR.

cc: Dennis Gibbons; Cal EPA/DPR

Occupational Exposure and Risk Assessment of Sulfotepp

A. Hazard Identification

I. Acute Toxicology Categories

The toxicological database for sulfotepp (0,0,0,0-tetraethyl-dithio-diphosphate) is incomplete. The sulfotepp labels indicates that it is classified as restricted-use due to very high toxicity to humans.[1]

II. Other Endpoints of Concern

No route-specific data were available to obtain a short- or intermediate-term NOEL for dermal exposures. No route-specific EPA-reviewed data were available to obtain a NOEL for inhalation exposures.

a. Intermediate-term dermal endpoint: Since an acceptable route-specific study is not available to assess sulfotepp dermal exposure and risk, the Agency is basing the following *dermal* risk assessment on the results of the subchronic feeding study in dogs (MRID 42955601) that has been reviewed and graded as *acceptable* by the Agency (P. Hurley memo, 7/13/95).[2]

In the study, male and female beagle dogs were given E393 (sulfotepp) in the diet at concentrations of 0, 0.014, 0.11, 0.55, or 2.75 mg/kg/day in males, and 0.014, 0.12, 0.57, or 3.07 mg/kg/day in females. No treatment-related effects were observed for food consumption, body weight gain, hematology, gross or microscopic pathology, or most clinical chemistry parameters. Occasional diarrhea and vomiting were seen in dogs receiving 0.55/0.57 mg/kg/day and these signs were common in dogs given 2.75/3.07 mg/kg/day. Mean cholinesterase activities in erythrocytes and plasma were statistically ($p < 0.05$) reduced in high dose males and females as compared to controls throughout the entire study. There was also a dose-responsive decrease in plasma cholinesterase activity beginning with the 0.11 mg/kg/day male group and the 0.014 mg/kg/day female group. No differences were seen at necropsy in brain cholinesterase activity of any treated group as compared to controls.

Under the conditions of this study, the LOEL for clinical signs of toxicity from dietary exposure to E393 is 0.55 mg/kg/day and the NOEL is 0.11 mg/kg/day. Based on the dose responsive inhibition of 10% or greater of plasma cholinesterase activity, the LOELs for male and female Beagle dogs are 0.11 mg/kg/day, and the NOEL for males is 0.014 mg/kg/day. The NOEL of 0.014 mg ai/kg/day is used in the risk assessment for evaluating *intermediate-term* dermal risks to postapplication workers. A NOEL for female cholinesterase activity was not identified.

b. Short-term dermal endpoint: To estimate a surrogate *short-term* NOEL for sulfotepp, EPA used data for ethyl parathion, another organophosphate pesticide that is believed to be similar in nature to sulfotepp. The intermediate-term NOEL for ethyl parathion is 0.0024 mg/kg/day based on a 180-day oral toxicity study in dogs that showed reduced cholinesterase activity by week 6.[3] The short-term NOEL for ethyl parathion is 0.025 mg/kg/day based on an oral acute neurotoxicity study on rats in which plasma and RBC cholinesterase inhibition was observed. The short-term NOEL is, therefore, approximately 10 times higher than the intermediate-term NOEL for ethyl parathion. Assuming that the ratio of short-term to intermediate-term NOEL would be the same for sulfotepp as it is for ethyl parathion, the short-term NOEL for sulfotepp was estimated to be 0.14 mg ai/kg/day. This value was used in the risk assessment for evaluating short-term dermal risks to postapplication workers.

c. Dermal absorption: The NOELs for the dermal short- and intermediate-term risk assessments are based on an oral study. EPA notes that OSHA's sulfotepp PEL has a *skin notation* because data indicate that sulfotepp penetrates the skin in amounts sufficient to induce systemic toxicity.[4] The National Institute for Occupational Safety and Health (NIOSH) concurs with the OSHA PEL with *skin notation* for sulfotepp.[4] In addition, the American Conference and Governmental Industrial Hygienists[4] (ACGIH) has established a threshold limit value (TLV) for sulfotepp and also placed a *skin notation* on the value. Therefore, in lieu of dermal absorption data and in light of the *skin notation* on the PEL/TLV, EPA is assuming 100 percent dermal absorption. This is consistent with the assumption of 100 percent dermal absorption used by EPA for ethyl parathion risk assessments.

d. Inhalation Endpoint: The American Conference and Governmental Industrial Hygienists[4] (ACGIH) has established a threshold limit value (TLV) based on the results of a sulfotepp subchronic inhalation study[5] published in 1974 (MRID 43356701 and 43550601). Although this submission has not been reviewed by the Agency, the endpoint and dose (NOEL) reported in this study are the basis for the following *inhalation* risk assessment.

For 12 weeks, 4 groups of 10 male and 10 female rats were exposed to different aerosol concentrations of sulfotepp for 6 hours daily/5 days per week. The concentrations were 0, 0.89, 1.94, and 2.83 mg/m^3 and cholinesterase in plasma and erythrocytes was determined at week 1, 4, 6, 8, and 12. Laboratory examinations were also performed at week 12. Sulfotepp concentrations were measured by gas chromatograph. The exposure to sulfotepp aerosol at up to 2.83 mg/m^3 did not cause any significant changes in appearance, behavior, or body weight gain. The hematological values and serum-enzyme activities as well as serum concentrations of urea, creatinine, protein, and bilirubin were not altered and there was no significant change in the composition of the urine. The sulfotepp concentrations of 0.89 and 1.94 mg/m^3 (study NOEL) caused no depression of cholinesterase activity in plasma and erythrocytes and at 2.83 mg/m^3 (LOEL) caused significant inhibition of plasma cholinesterase activity. On the basis of this study, EPA established an inhalation NOEL of 1.94 mg/m^3 for sulfotepp.

e. **Chronic-term endpoints**: Chronic toxicity studies have not been required or reviewed by the Agency. Given the nature of sulfotepp use patterns, no chronic exposures are anticipated.

f. **Cancer endpoint**: Carcinogenicity studies have not been required or reviewed by the Agency.

g. **PEL/TLV**: The Occupational Safety and Health Agency (OSHA) has established a permissible exposure limit (PEL) as a time-weighted average of 0.2 mg/m^3 for sulfotepp.[4] The National Institute for Occupational Safety and Health (NIOSH) concurs with the OSHA PEL.[4] In addition, the American Conference and Governmental Industrial Hygienists (ACGIH) has established a threshold limit value (TLV) as a time-weighted average of 0.2 mg/m^3 for sulfotepp.[4]

h. **IDLH**: NIOSH has established a value of 35 mg/m^3 for sulfotepp as a level that is immediately dangerous to life or health (IDLH).[4]

i. **Margin of exposure**: A margin of exposure (MOE) of 100 or greater is generally considered adequate by the Agency for both the short- and intermediate-term dermal and inhalation risk assessments. This includes a 10-fold safety factor for interspecies variability and a 10-fold safety factor for intraspecies variability. However, due to the lack of acceptable data for sulfotepp, HED has not determined an MOE that is considered adequate.

III. Data History

On September 30, 1988, the Agency issued a Registration Standard for the active ingredient sulfotepp. The standard required that registrants submit the following generic toxicological data for the technical grade of the active ingredient:

Acute Oral Toxicity - Rat (GL 81-1)
Acute Dermal Toxicity - Rabbit (GL 81-2)
Acute Inhalation Toxicity - Rat (GL 81-3)
Eye Irritation - Rabbit (GL 81-4)
Dermal Irritation - Rabbit (GL 81-5)
Dermal Sensitization - Guinea Pig (GL 81-6)
Acute Delayed Neurotoxicity - Hen (GL 81-7)
21-Day Dermal - Rabbit (GL 82-2)
90-Day Inhalation - Rat (GL 82-4) (Note: HED currently believes that a 21-day inhalation study might be more appropriate.)
Teratology - one species (GL 83-3)
Mutagenicity Studies (GL 84-2)
Reserved: 90-Day Dermal - Rat (GL 82-3)
Reserved: Pending Results of GL 81-7: 90-Day Neurotoxicity (GL 82-5)

In addition, in 1991, the Agency issued a data call-in (DCI) for sulfotepp neurotoxicity data (Guidelines 81-8-SS, 82-5(b), and 85-7-SS).

The registrants (Fuller System, Inc. and Plant Products Corporation) committed to provide the required data and to this end submitted studies purchased from the technical supplier (Bayer).

In the interim, the Agency has received and completed the review (P. Hurley memo, 7/13/95) of three studies submitted collectively in response to the DCI. The three studies are; 1) a subchronic feeding study in the dog (82-1b), 2) an acute oral toxicity in the hen, and 3) an NTE/cholinesterase study in the hen. The subchronic dog study was classified as "Core Minimum" and is considered acceptable for regulatory purposes. The hen studies were classified as "Core Supplementary" and may be used in support of an acute delayed neurotoxicity study but the studies are not considered acceptable for regulatory purposes.

Per instructions, other submitted toxicology data have *not* been reviewed by HED. However, this data has been *screened* by HED and the following studies *may* be acceptable (if reviewed) for regulatory purposes; 1) a special study on effect of sulfotepp on ChE in newborn rats (GL 81-1), 2) skin sensitization in the guinea pig (GL 81-6), 3) clastogenic effects on human lymphocytes (GL 84-2), 4) ames test (GL 84-4), and 5) a supplemental developmental toxicity study (GL 83-3). Other submitted data, screened (but not reviewed) has been designated by HED as *not* acceptable for regulatory purposes.

IV. Calculating Risks

a. Dermal risks: Dermal risk was estimated by dividing the dermal endpoint (NOEL) by the estimated daily dermal dose.

b. Inhalation risks: Inhalation risk was estimated by calculating a route-specific MOE.[6] The route-specific MOE is preferred over a route-to-route MOE, because there is no need to estimate the percentage of absorption or adjust for metabolism or any other pharmacokinetic parameters. The Science Advisory Panel (SAP) and HED Exposure Science Advisory Committee (SAC) have endorsed the use of route-specific MOEs whenever possible because they are more accurate and are easy to combine with MOEs from other routes of exposure -- even when they have dissimilar uncertainty factors.[6]

A route-specific MOE is calculated by dividing a NOEL for a route of specific exposure (e.g., inhalation) that is derived from an animal study by the estimated human exposure for the same route of exposure. Since the units are the same (e.g., mg/m^3 for inhalation), they cancel out to yield a unitless MOE. Precision is enhanced by accounting for differences in:

- $\mathbf{D_A}$ Duration of daily exposure for test animals (hours/day)
- $\mathbf{D_H}$ Duration of daily exposure for humans (hours/day)
- $\mathbf{AF_A}$ Activity factor for test animals (default value of 1 is assigned)

AF_H Activity factor for humans (accounts for activity-related variations in respiration)

The activity factor accounts for increased exposure (e.g., respiratory rate) due to increased activity. The activity factor for the test animals is assigned a default value of 1, since animals in a test chamber are assumed to have low activity levels. The activity factor for humans is a ratio of the estimated human respiratory rate while performing certain activities to the estimated human respiratory rate at rest. The activity-specific human respiratory rates are listed in the EPA's *Exposure Factors Handbook* published in 1997.

A route-specific inhalation MOE is calculated as follows:

$$MOE = \frac{NOEL\ (mg/m^3) \times D_A \times AF_A}{Human\ Airborne\ Concentration\ (mg/m^3) \times D_H \times AF_H}$$

IV. Epidemiological information

Four databases have been consulted for the poisoning incident data on the active ingredient sulfotepp.[7]

a. OPP Incident Data System (IDS): The Incident Data Systems indicates two sulfotepp-related incidents:

- An individual entered two locked greenhouses to which she had a key. Both greenhouses had been treated with sulfotepp earlier that day but neither greenhouse was posted. After about 10 minutes she experienced nausea, difficulty breathing, and burning lips and eyes. She was seen in a local emergency room. No further information on the disposition of this case is available.

- In 1995 an applicator to a Texas greenhouse was exposed to sulfotepp and developed headache, nausea, diarrhea, vomiting, cough, dizziness, sweating, fatigue, abdominal pain, anxiety, muscle aches, chest tightness, drowsiness, restlessness, shortness of breath, and excessive salivation. Blood cholinesterase levels taken 12 hours after the exposure were within the normal range. The applicator reported wearing the required protective equipment including full body suit and full face respirator. His respirator had been fit tested earlier that month and no leaking was detected. However, the worker did report being able to smell the compound. When questioned two of the other three applicators in the same greenhouse reported that they also smelled the chemical and felt nauseated. A subsequent investigation by the State Health department determined that the PPE used was appropriate and in good working order and that all product label directions had been followed. During their on site investigation the four workers again applied sulfotepp and three of the four smelled the

chemical and the same worker again developed symptoms though less severe. A survey of 43 companies that use sulfotepp in greenhouse applications identified three companies that reported workers who had become ill though none sought medical attention. As a result of this investigation the Texas Department of Health recommended appropriate supplied air respirators and training in proper use of fumigants as part of the licensure requirements for greenhouse pesticide applicators. Other procedures recommended involved reducing exposure by pre-punching canisters so that all of them could be ignited at once with minimal time spent with workers carrying ignited canisters or spending unnecessary time in the greenhouse while the smoke is being produced. A copy of the Texas report (Morbidity and Mortality Weekly Report 45:780-782, 1996) and rebuttal prepared by Fuller System, Inc. are attached to this review.

b. Poison Control Centers: There were a total of 40 sulfotepp cases in the PCC database. Of these, 23 cases were occupational exposure; 22 (96%) involved exposure to sulfotepp alone and 1 (4%) involved exposure to multiple chemicals, including sulfotepp. There were a total of 14 adult non-occupational exposures; all of which involved this chemical alone. (Workers who were indirectly exposed (not handlers) were classified as non-occupational cases.) Three cases were reported in children under the age of six years. Out of 37 reported cases involving adults, there were no life-threatening cases and symptoms were less commonly reported than for other cholinesterase inhibitors. .

c. California Department of Food and Agriculture (replaced by the Department of Pesticide Regulation in 1991): There were 17 cases involving sulfotepp submitted to the California Pesticide Illness Surveillance Program from 1982 to 1995. In 16 of these cases, sulfotepp was used alone and was judged to be responsible for the health effects. None of the individuals were reported hospitalized between 1982 and 1995 and two individuals were reported off work for one day. All 16 persons had systemic illnesses. Three cases occurred in 1984 when leaked to a work site outside the greenhouse. These cases appear to represent a cluster episode at one work site. Another eight cases occurred in 1995 when material leaked from cracks in the greenhouse. The fumes drifted 200 to 300 feet to a residential area resulting in cluster of 8 poisonings. Exposure to residue was reported in three cases: one involving a worker who returned two hours after treatment and did have on some protective clothing; a second who returned to a greenhouse after 15 hours and after the greenhouse had been ventilated only one hour; and a third case was a truck driver loading plants possibly exposed to residual vapors at an unknown time after application.

d. National Pesticide Telecommunications Network (NPTN): On the list of the top 200 chemicals for which NPTN received calls from 1984-1991 inclusively, sulfotepp ranked 197th and was reported to be involved in eleven human incidents.

e. Summary/Conclusions: Relatively small numbers of reports of illness from sulfotepp have been identified. Two incidents have been reported to the Incident Data System (1992-

1998), 40 incidents to the nation's Poison Control Centers (1985-1992), 16 incidents to the California Pesticide Illness Surveillance Program (1982-1995), and 11 incidents to the National Pesticide Telecommunications Network (1984-1991). The California reports suggest that drift outside of improperly sealed greenhouses can pose a hazard to persons nearby (up to 100 meters). Exposure to residue when reentering has also led to development of symptoms. The most controversial case is the Texas report of poisoning in applicators using proper protective equipment and following proper precautions. In one instance workers reported smelling the product and one developed symptoms while health investigators were on site observing the application. One of the registrants questions whether the symptoms were do to sulfotepp or due solely to smoke inhalation. A survey in Texas of 43 establishments determined that 3 (7%) had workers who reported experiencing illness associated with their use of sulfotepp.

B. Use and Usage

I. Occupational Use Products

a. Type of Pesticides/Target Pests: Sulfotepp is an organophosphate insecticide used for control of certain ornamental pests such as insects and related organisms, mollusks, fouling organisms and miscellaneous invertebrates), mites, red spider mites, and thrips.

b. Formulation types and percent active ingredient: Sulfotepp is formulated as impregnated material in smoke generators (canisters) containing 14 to 15 percent active ingredient.[8]

c. Registered use sites: Sulfotepp is a restricted-use pesticide used in greenhouses only (EPA Reg. No. 8241-10; 1322-38).

d. Application rates: The application rate is 0.0033 pound of active ingredient per 1,000 cubic feet (Plantfume 103™; EPA Reg. No. 8241-10).

e. Methods and types of equipment used: The sulfotepp smoke generators are placed in the greenhouse and then ignited using inserted sparklers to generate a dense white smoke for fumigation.

f. Timing and frequency of applications: Fumigation with sulfotepp may be repeated every three days until the greenhouse is pest free.

g. Additional notes on current use: Sulfotepp is used primarily just before marketing of the plants as a final cleanup of pests to ensure the pest-free status of plants. It is effective against the three most important greenhouse arthropod pests: aphids, spider mites, and whiteflies. The primary use for sulfotepp in states such as California, Michigan, New York, Ohio, Pennsylvania, and Texas is for whitefly control in mature poinsettias. In addition,

sulfotepp is recommended specifically for use on rose, stock, snapdragon, orchids, hydrangea, geranium, gardenia, foliage plants, cyclamen, chrysanthemum, carnation and azalea in New Jersey. Sulfotepp is also recommended in a number of state floricultural pesticide guides for ornamentals in general. In California, one or two applications of sulfotepp are also used per crop (three crops per year) on gerbera daisies and hibiscus. In Pennsylvania sulfotepp is used by some growers in the spring on bedding plants, primarily cinerarias and calceolarias as well as poinsettias later in the year and likely on some roses.[9] Sulfotepp is usually applied in the evening. After ventilation the next morning following WPS guidelines, unrestricted entry is allowed.

II. Residential Use Products

There are no currently registered homeowner products for sulfotepp. However, current labels do *not* prohibit application in residential greenhouses by certified commercial applicators.

C. Handler Exposures and Risks

I. Handler Exposure Scenarios

EPA has determined there are potential exposures to handlers during usual use patterns associated with sulfotepp. Based on the use patterns, two major occupational scenarios were identified: (1) opening/lighting of canisters, and (2) reentering fumigated greenhouse to open vents and dispose of canisters.

No guideline/good laboratory practices (GLP)-acceptable chemical-specific handler exposure data has been submitted to the Agency. Available data in PHED (Pesticide Handlers Exposure Database) do not reflect the use patterns of sulfotepp.

a. Estimating dermal exposure to handlers: For handlers, dermal exposures are assumed to be small relative to the exposures and risks from inhalation. This assumption is based on the use pattern where potential dermal exposure is limited to possible contact with the sulfotepp powder (1) while opening the canisters and inserting the sparkler, (2) an accidental spill during lighting of a canister or retrieval of an unlit canister, and (3) possible contact with residue on the outside of a spent canister. These dermal exposures are expected to be relatively infrequent and of relatively short duration in comparison with the estimated inhalation exposure time and the potentially high air concentrations of sulfotepp during handling activities. Therefore, only inhalation exposure and risk were estimated for handlers.

b. Estimating inhalation exposure to handlers: EPA assessed a range of possible air concentration levels to which handlers could be exposed. A 1980 study[10] by Williams et al. published in the American Industrial Hygiene Association Journal (AIHAJ), measured on-site real-time sulfotepp air levels in a greenhouse being fumigated. In this study, the air

concentration measured approximately 4 hours after the start of fumigation and before opening the vents and aerating the greenhouse was 2.7 mg/m^3 (200 ppb). This level was selected to represent a reasonable level possibly encountered by handlers igniting the canisters or entering following fumigation to activate the ventilation system.

EPA estimated the maximum air concentration levels potentially encountered by handlers by assuming that during fumigation all of the active ingredient in the smoke canister enters the greenhouse air at the label application rate. This concentration can be calculated as follows:

$$Air\ concentration\left(\frac{mg\ ai}{cubic\ meter}\right) = Application\ rate\left(\frac{lb\ ai}{cubic\ feet}\right) * Conversion\ Factors\left(\frac{mg\ ai}{lb\ ai} * \frac{cubic\ feet}{cubic\ meter}\right)$$

The maximum potential air concentration is 52.5 mg ai per m^3 based on the label application rate.

c. Other assumptions: The following assumptions were used to complete the handler exposure and risk assessment:

- Handlers are assumed to be exposed intermittently to sulfotepp (e.g., up to one hour on the day of application; up to one hour on the following day for venting; then repeating the exposure for an application on day three). Therefore, short-term risks are assessed, but not intermediate-term or chronic risks.

- The exposure period for handlers would depend on the size of the greenhouse and, therefore, how many canisters must be lit. EPA estimates that the exposure period would likely to range from approximately 30 minutes for smaller greenhouses up to an hour for larger greenhouses. A single handler could treat multiple greenhouses per day, so this range may actually underestimate actual exposure duration.

- The same sulfotepp air concentration is assumed to be encountered by handlers when they apply/light smoke canisters and when they enter the treated greenhouse to open vents and dispose of canisters. These two activities are considered as a single exposure scenario.

II. Handler Exposure and Non-cancer Risk Estimates

The estimates of sulfotepp air concentration to which handlers may be exposed are used to calculate the risk to those handlers. The route-specific inhalation MOE was calculated as follows:

$$NOEL\ (mg/m^3)\ x\ D_A\ x\ AF_A$$

$$MOE = \frac{\text{Inhalation NOAEL (mg/m}^3\text{) x } D_A \text{ x } AF_A}{\text{Human Airborne Concentration (mg/m}^3\text{) x } D_H \text{ x } AF_H}$$

where:

D_A Duration of daily exposure for test animals (hours/day)
D_H Duration of daily exposure for humans (hours/day)
AF_A Activity factor for test animals (default is 1)
AF_H Activity factor for humans (accounts for activity-related variations in respiration)

The activity factor for humans is based on the assumption that handler activities are most similar to the category titled sedentary.

Table 1 provides estimated inhalation risks to handlers based on the above assumptions and formula at baseline (i.e., without the use of personal protective equipment) and with risk mitigation (i.e., with the use of various types of respirators).

Table 1. Occupational Handlers' Inhalation Risks from Sulfotepp

	Air Concentration (mg ai/m^3)[a]	Respirator Protection Factor[b]	Human Exposure Duration (hr/day)[c]	Human Activity Factor[d]	Animal Exposure Duration (hr/day)[e]	Animal Activity Factor[f]	Animal Inhalation NOEL (mg/m^3)[g]	Inhalation MOE[h] (0.5 hr/1 hr)
Baseline (no respirator)	52.5	1	0.5/1	1.3	6	1	1.9	0.3/0.2
	2.7	1	0.5/1	1.3	6	1	1.9	6/3
Half-face organic-vapor-removing respirator	52.5	10	0.5/1	1.3	6	1	1.9	3/2
	2.7	10	0.5/1	1.3	6	1	1.9	65/32
Full-face organic-vapor-removing respirator	52.5	50	0.5/1	1.3	6	1	1.9	17/8
	2.7	50	0.5/1	1.3	6	1	1.9	320/160
Self-contained breathing apparatus	52.5	10,000	0.5/1	1.3	6	1	1.9	3,300/1,700
	2.7	10,000	0.5/1	1.3	6	1	1.9	65,000/32,000

a Air concentration of 52.5 mg ai/m^3 is the maximum theoretical air concentration based on label application rate (EPA Reg. No. 8241-10). Preventilation air concentration of 2.7 mg ai/m^3 (approximately 4 hours following the start of fumigation) represents the air concentration encountered by handlers when they enter the greenhouse to ventilate following fumigation as reported in the AIHAJ study *On site determination of sulfotepp air levels in a fumigating greenhouse*.[10]

b Respirator protection factor is the theoretical reduction in the sulfotepp concentration in air provided by respiratory protection worn by a handler from NIOSH Guide to Industrial Respiratory Protection.[11]
Baseline (represents handlers wearing no respirator) is assigned a protection factor of 1 (no protection);
Half-face organic-vapor-removing respirator is assigned a protection factor of 10. (90% protection);
Full-face organic-vapor-removing respirator is assigned a protection factor of 50 (98% protection);
Self-contained breathing apparatus is assigned a protection factor of 10,000 (99.99% protection).

c Human exposure duration is based on the estimate of handler exposures of 30 minutes to 1 hour.

d Human activity value based on assumption that handler activities are equivalent to sedentary activities. Based on activity-specific inhalation rates listed in EFHB; U.S. EPA 1997.[13]

e Animal exposure duration of 6 hours per day is the daily exposure duration the test animals were subjected to in the study from which the inhalation endpoint is taken.

f Animal activity factor of 1 is based on the assumption that the test animals were at rest during the exposure study from which the inhalation endpoint is taken.

g Animal inhalation NOEL is 1.9 mg/m^3 in the animal inhalation exposure study.[5]

h MOE = (animal inhalation NOEL X animal exposure duration X animal activity factor) / (air concentration X human exposure duration X human activity factor) X respiratory protection factor

III. Handler Exposure and Cancer Risk Estimates

No carcinogenicity studies have been required or reviewed by the Agency. Therefore, the carcinogenic risks from exposure to sulfotepp were not assessed.

IV. Summary of Risk Concerns for Handlers, Data Gaps, and Confidence in Exposure and Risk Estimates

a. Risk concerns for handlers: Table 1 presents estimates of occupational handlers' inhalation risks from sulfotepp. Due to the lack of acceptable data for sulfotepp, HED has not determined an MOE that is considered adequate. Results indicate:

- At baseline protection (no respirator), the MOEs are less than 100; the highest MOE = 6.
- With a half-face organic vapor-removing respirator with a dust/mist prefilter, the MOEs are less than 100; the highest MOE = 65.
- With the full-face organic vapor-removing respirator with a HEPA prefilter, the MOEs are less than 100 at the 52.5 mg ai/m^3 air concentration level (highest MOE = 17/8); MOEs are greater than 100 at the 2.7 mg ai/m^3 level (MOE = 320/160).
- With the self-contained breathing apparatus, the MOEs are much greater than 100 at both air concentration levels; the lowest MOE = 1700.

b. Data Quality and Confidence in Assessment: The risk estimate for handlers is based on several assumptions that reflect on the confidence of this assessment:

- If no personal protective equipment (e.g., gloves, double-layer body protection) is worn, dermal exposure may be greater than assumed since there are opportunities for dermal contact with the sulfotepp during the lighting of the canisters (e.g., puncturing the canisters, inserting the sparkler, spilling) and during removal of the canisters following application (e.g., residue on canister, spilling contents of unlit canister).
- The toxicological database is inadequate. The inhalation endpoint (NOEL of 1.9 mg/m^3) is derived from data generated in 1974 that was used to established the TLV and PEL, but the data do not meet EPA guidelines or GLP requirements.
- The duration of exposure is based on the best professional judgement. No actual data are available.
- The air concentration levels are estimates of possible exposures. One is the maximum theoretical air concentration based on the labeled application rates. The other air concentration level was taken from a 1980 AIHAJ study and was a measurement of

sulfotepp air concentration conducted approximately 4 hours following the start of fumigation but prior to aerating the greenhouse. The study does not meet EPA guidelines or GLP requirements.

- EPA has concerns about whether the AIHAJ study was conducted in conformity with current sulfotepp labeling directions and uncertainties about study conditions.

  --In the AIHAJ study, 22 grams of sulfotepp were used to fumigate a greenhouse with a volume of 450 m^3, which is equivalent to a rate of 0.048 g ai/m^3. The current sulfotepp label rate is 0.0525 g ai/m^3 (7 ounces per 20,000 cubic feet).

  --In the AIHAJ study, the door was sealed and entry was prohibited after fumigation. Reentry was allowed to partially open vents and remove canisters four hours after ignition of the fumigant. There were no internal fans operating in the greenhouse and dissipation of sulfotepp was by convection and diffusion only. Currently one sulfotepp product label (Plantfume 103) directs users to "close all greenhouse vents prior to use," and "maintain treatment conditions overnight," or "open ventilators 2 to 3 hours after fumigation on tender plants." The other sulfotepp product label (Fulex Dithio Smoke) directs users to "close all greenhouse vents prior to use," "it is advisable to ventilate the greenhouse within twelve hours from the start of treatment --ventilation at the end of eight hours is more desirable if possible."

  --In the AIHAJ study, the relative humidity ranged from 40 to 60 percent (not controlled) and temperature was maintained at 21°C during the day and 10°C during the night (11 p.m. to 7 a.m.). Both sulfotepp product labels indicate that the relative humidity should be kept low and that temperatures within the greenhouse should be maintained between 70°F and 90°F (21°C to 32°C).

  --In the AIHAJ study, the number and the size of vents were not specified, which would have had effects on the dissipation of sulfotepp residues. Also the time at which the vents were opened and the number of vents opened was not specified.

C. Postapplication Exposures and Risks

I. Postapplication Exposure Scenarios

EPA has determined there are potential postapplication dermal and inhalation exposures to workers during usual work practices following applications of sulfotepp. Two major occupational scenarios were identified: (1) entry to perform watering or other routine low-exposure tasks and (2) entry to perform harvesting, transferring, or other high-exposure tasks. Since one of the primary uses is just before marketing to ensure the pest-free status of plants, EPA assumes routine entry to perform hand labor tasks, such as watering, tending, harvesting, and preparing plants for shipment, would be initiated as soon as possible, normally the morning following an evening application. EPA notes that label instructions and other use information indicate that applications may be repeated every three days until the plants are free of pests. In practice, two to three applications at three-day intervals is usual and workers might be expected to have daily exposures for more than a week, depending on how rapidly sulfotepp dissipates. Therefore, intermediate-term as well as short-term risks should be assessed.

No guideline/GLP-acceptable sulfotepp-specific postapplication exposure data were submitted or reviewed by EPA in support of the reregistration of sulfotepp.

a. Estimating dermal exposure to postapplication workers: Data reported in a 1986 degradation study conducted by the California Department of Food and Agriculture (CDFA)[14] were used for estimating sulfotepp postapplication dermal exposures and risks. The CDFA study reported dislodgeable foliar residue (DFR) values for sulfotepp on poinsettias at two sites and on geraniums at one site. DFR data for the poinsettias at site 2 were chosen as representative DFRs for the dermal exposure assessment. DFR values for poinsettias at site 1 were slightly lower and DFR values for geraniums at site 3 were slightly higher. Similar DFR values were found in a 1978 study[15] published in the Journal of Environmental Science and Health that measured "likely to collect on the upper surfaces of exposed leaves." The average surface concentration measured in that study 24 hours after the start of the fumigation (0.021 $\mu g/cm^3$) is similar to the DFR measured at 24 hours in the CDFA study (0.02 $\mu g/cm^3$). Neither study meets current U.S. EPA guidelines or GLP criteria.[16]

In lieu of sulfotepp-specific data on transfer coefficients, a default transfer coefficient of 1,000 was used to represent low dermal exposure activities (tending and watering) and 10,000 was used to represent relatively high dermal exposure activities (harvesting and preparing for shipping).

b. Estimating inhalation exposure to postapplication workers: EPA assessed a range of possible air concentration levels to which postapplication workers could be exposed. A 1980 study[10] by Williams et al. published in the American Industrial Hygiene Association Journal (AIHAJ) measured on-site real-time sulfotepp air levels in a fumigated greenhouse. In this study, the air concentration was measured starting approximately 4 hours after the start of fumigation and before opening the vents to aerate the greenhouse, continuing until approximately 48 hours

following the start of fumigation. EPA selected a range of air concentration levels that were measured from the time initial post-fumigation ventilation was complete and continuing through the 48 hour period. The highest post-ventilation air concentration level was 0.34 mg ai/m^3 (25 ppb), the lowest steady post-ventilation level was 0.040 mg ai/m^3 (3 ppb), and a reelevated post-ventilation level (an increased air concentration level apparently caused by watering the plants) was 0.15 mg ai/m^3 (11 ppb). The AIHAJ study also measured sulfotepp air concentration levels 18 days following application to be 0.0013 mg ai/m^3 (0.097 ppb). EPA used this level as a baseline air concentration level.

c. Other assumptions: The following assumptions were used to complete the postapplication exposure and risk assessment:

- Postapplication workers are assumed to be exposed continuously to sulfotepp (e.g., eight hours per day for a week or more), particularly when application is repeated every three days for two to three applications. Therefore, short- and intermediate-term risks are assessed.

- Average postapplication work period is 8 hours per day.

- Average body weight is 70 kg for an adult handler.

- One hundred percent dermal absorption.

II. Postapplication Exposure and Non-Cancer Risk Estimates

a. Postapplication dermal risk estimates: The calculations of postapplication daily dermal exposures to sulfotepp were used to calculate the daily doses, and hence the risks, to workers reentering the fumigated greenhouse. Potential daily dermal exposure was calculated using the following formula:

$$Daily\ Dermal\ Exposure\left(\frac{mg\ ai}{day}\right) = Dislodgeable\ Foliar\ Residue\left(\frac{ug\ ai}{square\ centimeter}\right) x\ Transfer\ Coefficient\left(\frac{sqaure\ centimeter}{hour}\right) x\ 0.001\ mg/\mu g\ x\ Exposure\ Duration\left(\frac{hours}{day}\right)$$

The potential daily dermal dose was calculated using a 70 kg body weight as follows:

$$Daily\ Dermal\ Dose\left(\frac{mg\ ai}{kg/day}\right) = Daily\ Dermal\ Exposure\left(\frac{mg\ ai}{day}\right) x\left(\frac{1}{Body\ Weight\ (kg)}\right)$$

The short-term MOE was calculated using the estimated NOEL value of (0.14 mg ai/kg/day) and the intermediate-term MOE was calculated using the NOEL value (0.014 mg ai/kg/day). The following formula describes the calculation of the MOE:

$$MOE = \frac{NOEL\left(\frac{mg\ ai}{kg/day}\right)}{Daily\ Dermal\ Dose\left(\frac{mg\ ai}{kg/day}\right)}$$

Table 2 provides estimated short- and intermediate-term exposures and risks to postapplication workers.

b. Postapplication inhalation risk estimates: The estimates of sulfotepp air concentration to which postapplication workers may be exposed are used to calculate the risk to those workers. The route-specific inhalation MOE was calculated as follows:

$$MOE = \frac{NOEL\ (mg/m^3) \times D_A \times AF_A}{Human\ Airborne\ Concentration\ (mg/m^3) \times D_H \times AF_H}$$

where:

D_A Duration of daily exposure for test animals (hours/day)
D_H Duration of daily exposure for humans (hours/day)
AF_A Activity factor for test animals (default is 1)
AF_H Activity factor for humans (accounts for activity-related variations in respiration)

The activity factor for humans is 2.2 for postapplication workers based on the assumption that an equal mix of light and moderate activities are performed.[6]

Table 3 provides estimated inhalation risks to postapplication workers based on the above assumptions, the range of post-ventilation air concentration levels, and the formula.

c. Postapplication total risk estimates: Since both the dermal and inhalation risks to postapplication workers are based on the same toxicological endpoint of concern -- cholinesterase inhibition -- the estimated dermal and inhalation risks can be combined to obtain total estimated risk to workers. The total MOE was calculated using the following formula:

$$Total\ MOE = \frac{1}{\left(\frac{1}{MOE_{dermal}}\right) + \left(\frac{1}{MOE_{inhalation}}\right)}$$

The short-term total risk is calculated by adding the reciprocals of the short-term dermal MOE and the inhalation MOE and dividing the total into one. Intermediate-term total risk is calculated by adding the reciprocals of the intermediate-term dermal MOE and the inhalation MOE and dividing the total into one.

d. Postapplication cancer risk estimates: No carcinogenicity studies for sulfotepp were required or reviewed by the Agency. Therefore, the carcinogenic risks from postapplication exposure to sulfotepp were not assessed.

e. Summary of Postapplication Risk Concerns, Data Gaps, and Confidence in Exposure and Risk Estimates

i. Postapplication dermal risk concerns: Short- and intermediate-term dermal postapplication risk concerns are presented in Table 2. Due to the lack of acceptable data for sulfotepp, HED has not determined an MOE that is considered adequate. Results indicate:

- Short-term dermal MOEs for *low exposure* activities are greater than 100 (MOE = 120) at 38 hours following fumigation. MOEs are less than 100 at both 15 hours and 24 hours following fumigation.
- Short-term dermal MOEs for *high exposure* activities are less than 100 at 15 hours, 24 hours, and 38 hours following fumigation.
- Intermediate-term dermal MOEs for *low exposure* activities are less than 100 at 15 hours, 24 hours, and 38 hours following fumigation.
- Intermediate-term dermal MOEs for *high exposure* activities are less than 100 at 15 hours, 24 hours, and 38 hours following fumigation.

ii. Postapplication inhalation risk concerns: Inhalation postapplication risks are presented in Table 3. Due to the lack of acceptable data for sulfotepp, HED has not determined an MOE that is considered adequate. Results indicate that inhalation MOEs are less than 100 (<20) for all air concentrations measured within 48 hours of fumigation and after initial ventilation. The MOE at baseline air concentration measured 18 days following application is greater than 100 (500).

iii. Postapplication total risk concerns: Total postapplication risks are presented in Table 4. Due to the lack of acceptable data for sulfotepp, HED has not determined an MOE that is considered adequate. Results indicate that:

- Total short-term MOEs are less than 100 (ranging from 1 to 14) at all air concentration levels for both low and high exposure activities up to 38 hours following fumigation.
- Total intermediate-term MOEs are less than 100 (ranging from 0.3 to 7) at all air concentration levels for both low and high exposure activities up to 38 hours following fumigation.

iv. Data Quality and Confidence in Assessment: The risk estimates for postapplication workers is based on several assumptions that reflect on the confidence of this assessment:

- Inhalation and dermal exposure and risk may be even higher after the second or third application due to accumulation of sulfotepp in the greenhouse.

- A working period of 8 hours per day was assumed, which might result in overestimation of the risks for some activities.

- For the dermal assessment:

  --The short-term dermal NOEL is an estimate derived from an intermediate-term dermal NOEL that is based on data from an oral study.

  --For deriving the short-term NOEL for sulfotepp, a short-term to intermediate-term NOEL ratio of 10 for ethyl parathion was used. However, the intermediate-term NOEL for ethyl parathion was based on cholinesterase activity reductions observed by week 6 as opposed to 13 weeks in the dog study for sulfotepp. In addition, there may be differences between sulfotepp and ethyl parathion in terms of the toxifying mechanism in humans, and there is uncertainty resulting from extrapolation from dogs to humans, and variability within dogs.

  --Transfer coefficients of 1,000 and 10,000 for low and high exposure activities respectively were assumed; however, there were no data available that could verify the selection of these values.

  --Dislodgeable foliar residue (DFRs) values were obtained from a 1986 degradation study[14] conducted by California Department of Food and Agriculture (CDFA). However, EPA review[16] found the study to be unacceptable to fulfill the requirements for guideline 875.21 (DFR) and is not upgradeable to an acceptable study. It was not performed under GLP conditions and there was no GLP process imposed. In addition, factors that could have affected sulfotepp residue levels were not documented in entirety in this study. Finally, CDFA indicated to EPA that the study should not be used to support any regulatory action and that California itself would not accept this study to support any type of regulatory action.

  --Dislodgeable foliar residue values are available only for the first 38 hours following fumigation. These values result in MOEs less than 100. No DFR data are available to assess how long following fumigation when dermal exposures and risks would be greater than 100.

- For the inhalation assessment:

--The endpoint (NOEL of 1.9 mg/m^3) is derived from data generated in 1974 that is not a guideline/GLP-acceptable study.

--The postapplication air concentration levels were taken from a 1980 AIHAJ study that is not a guideline/GLP-acceptable study. EPA has concerns whether the AIHAJ study was conducted in conformity with current sulfotepp labeling directions and has uncertainties about study conditions (see *Data Quality and Confidence in Assessment* in the handler exposure and risk assessment).

Table 2. Postapplication Dermal Exposures and Risks to Occupational Workers from Sulfotepp

Exposure Scenario	Dislodgeable Foliar Residues (μg ai/cm^2)[a]	Transfer Coefficient (cm^2/hr)[b]	Exposure Duration (hr/day)[c]	Daily Dermal Exposure (mg ai/day)[d]	Daily Dermal Dose (mg ai/kg/day)[e]	Short-term MOE[f]	Intermediate-term MOE[g]
Low Exposure Activity (tending)	0.04 (15 hr after fumigation)	1000	8	0.32	0.0046	30	3
	0.02 (24 hr after fumigation)	1000	8	0.16	0.0023	61	6
	0.01 (38 hr after fumigation)	1000	8	0.08	0.0011	120	12
High Exposure Activity (harvesting, preparing for shipping)	0.04 (15 hr after fumigation)	10000	8	3.2	0.046	3	0.3
	0.02 (24 hr after fumigation)	10000	8	1.6	0.023	6	0.6
	0.01 (38 hr after fumigation)	10000	8	0.8	0.011	12	1.2

a Based on the DFR data from *A Study to Establish Degradation Profiles for Six Pesticides (Triforine, Endosulfan, Chlorothalonil, Sulfotep, Dodemorph Acetate, and Daminozide) Used on Ornamental Foliage in San Diego County California During Fall 1986.*[14]

b Transfer coefficients of 1,000 and 10,000 cm^2/ hour were used to represent low and high exposure activities, respectively.

c Based on 8 working hours per day.

d Daily dermal exposure (mg/day) = Dislodgeable Foliar Residues (μg/cm^2) x Transfer coefficient (cm^2/hr) x 0.001 mg/μg x Exposure duration (hr/day).

e Daily dermal dose (mg/kg/day) = Daily dermal exposure (mg/day) / Body weight (70 kg).

f Short-term MOE = Short-term oral NOEL (0.14 mg/kg/day) x 100% dermal absorption / daily dermal dose (mg/kg/day).

g Intermediate-term MOE = Intermediate-term oral NOEL (0.014 mg/kg/day) x 100% dermal absorption / Daily dermal dose (mg/kg/day).

Table 3. Postapplication Inhalation Risks to Occupational Workers from Sulfotepp

Inhalation Exposure Scenario	Air Concentration (mg ai/m^3)[a]	Human Exposure Duration (hr/day)[b]	Human Activity Factor[c]	Animal Exposure Duration (hr/day)[d]	Animal Activity Factor[e]	Animal Inhalation NOEL (mg/m^3)[f]	Inhalation MOE[g]
AIHAJ highest air concentration within 48 hours of fumigation and after initial ventilation	0.34 (25 ppb)	8	2.2	6	1	1.9	2
AIHAJ medium air concentration within 48 hours of fumigation and after initial ventilation (following watering)	0.15 (11 ppb)	8	2.2	6	1	1.9	4
AIHAJ lowest and steady air concentration within 48 hours of fumigation and after initial ventilation	0.040 (3 ppb)	8	2.2	6	1	1.9	16
AIHAJ baseline air concentration level (18 days after fumigation)	0.0013 (0.097 ppb)	8	2.2	6	1	1.9	500

a The air concentration ranges are based on results in the AIHAJ study *On site determination of sulfotepp air levels in a fumigating greenhouse*.[10]

b Human exposure duration is based on the estimate of worker postapplication exposures of 8 hours per day.

c Human activity value based on assumption that handler activities are equivalent to light work activities. Based on activity-specific inhalation rates listed in EFHB; U.S. EPA 1997.[13]

d Animal exposure duration of 6 hours per day is the daily exposure duration the test animals were subjected to in the study from which the inhalation endpoint is taken.

e Animal activity factor of 1 is based on the assumption that the test animals were at rest during the exposure study from which the inhalation endpoint is taken.

f Animal inhalation NOEL is 1.9 mg/m^3 in the animal inhalation exposure study.[5]

g MOE = (animal inhalation NOEL X animal exposure duration X animal activity factor) / (air concentration X human exposure duration X human activity factor)

Table 4. Postapplication Total (Inhalation plus Dermal) Risks to Occupational Workers from Sulfotepp

Exposure Scenario[a]	Short-term Dermal MOE[a]	Intermediate-term Dermal MOE[a]	Inhalation MOE[b]	Total Short-term MOE[c]	Total Intermediate-term MOE[d]
Low Exposure Activity (tending)	30 (15 hr after fumigation)	3	2 (AIHAJ high)	2	1
			4 (AIHAJ medium)	4	2
			16 (AIHAJ low)	10	3
	61 (24 hr after fumigation)	6	2 (AIHAJ high)	2	2
			4 (AIHAJ medium)	4	2
			16 (AIHAJ low)	13	4
	120 (38 hr after fumigation)	12	2 (AIHAJ high)	2	2
			4 (AIHAJ medium)	4	3
			16 (AIHAJ low)	14	7
High Exposure Activity (harvesting, preparing for shipping)	3 (15 hr after fumigation)	0.3	2 (AIHAJ high)	1	0.3
			4 (AIHAJ medium)	2	0.3
			16 (AIHAJ low)	3	0.3
	6 (24 hr after fumigation)	0.6	2 (AIHAJ high)	2	0.5
			4 (AIHAJ medium)	2	0.5
			16 (AIHAJ low)	4	0.6
	12 (38 hr after fumigation)	1.2	2 (AIHAJ high)	2	0.8
			4 (AIHAJ medium)	3	1
			16 (AIHAJ low)	7	1

a Based on Table 3: Postapplication Dermal Exposures and Risks to Occupational Workers from Sulfotepp.
b Based on Table 2: Postapplication Inhalation Risks to Occupational Workers from Sulfotepp.
c Short-term Total MOE is calculated by adding the reciprocals of the short-term dermal MOE and the inhalation MOE and dividing the total into 1.
d Intermediate-term Total MOE is calculated by adding the reciprocals of the intermediate-term dermal MOE and the inhalation MOE and dividing the total into 1.

D. Risk Characterization

I. General

a. Toxicological data: The toxicological data base for sulfotepp is incomplete. The sulfotepp labels indicates that it is classified as restricted-use due to very high toxicity to humans.[1]

No route-specific data were available to obtain a short- or intermediate-term endpoint for dermal exposures. EPA used data from a 13-week oral sulfotepp study on dogs to estimate a intermediate-term dermal endpoint and used that estimated endpoint and data from a similar organophosphate pesticide to estimate a short-term dermal endpoint. Dermal absorption is estimated to be 100 percent based on evidence that absorption through the skin can cause systemic effects in test animals. However 100 percent dermal absorption is likely to over-estimate dermal risks.

No guideline/GLP data were available to obtain an endpoint for inhalation exposures. EPA used data from a 1974 inhalation study in the published literature[5] to estimate inhalation risks for sulfotepp.

b. Exposure data: No sulfotepp-specific handler or postapplication exposure data has been submitted to the Agency. Available data in PHED (Pesticide Handlers Exposure Database) do not reflect the use pattern of sulfotepp.

i. Dermal exposures. EPA estimates that dermal exposures to handlers are likely to be relatively infrequent and of relatively short duration in comparison to the estimated inhalation exposure time and the potentially high air concentrations of sulfotepp during handling activities. However, some dermal exposure, particularly to the hands and forearms, is possible.

To estimate possible dermal exposures to postapplication workers, EPA used its expertise to estimate a range of default transfer coefficients (1,000 and 10,000 cm^2/hr) thought to capture the likely exposures from the common postapplication activities. To estimate the likely dislodgeable foliar residues (DFR) on the surface of treated plants, EPA used data from a 1987 California Department of Food and Agriculture study[14] even though EPA review[16] found the study to be unacceptable. It was not performed under GLP conditions, there was no QA/QC process imposed, and California indicated to EPA that the study should not be used to support any regulatory action.

ii. Inhalation exposures. To estimate inhalation exposures to handlers, EPA used a range of possible air concentration levels. At one end of the range, EPA estimated the maximum air concentration levels potentially encountered by handlers by assuming that during fumigation all of the active ingredient in the smoke canister enters the greenhouse air at the label application rate. At the other end of the range, EPA used data from a 1980 study in the published literature.[10] In this study, the air concentration was measured approximately 4 hours after the start of fumigation

and before opening the vents and aerating the greenhouse. This level was selected to represent the possible level encountered by handlers igniting the canisters or entering following fumigation to activate the ventilation system. EPA has concerns about whether the study was conducted in conformity with current sulfotepp labeling directions and about uncertainties about study conditions (see *Data Quality and Confidence in Assessment* in the handler exposure and risk assessment).

To estimate inhalation exposure to postapplication workers, EPA used data from the same 1980 study[10] in the published literature and not reviewed by the Agency. In this study, the air concentration was measured starting approximately 4 hours after the start of fumigation and before opening the vents to aerating the greenhouse and continuing until approximately 48 hours following the start of fumigation. EPA selected a range of air concentration levels that were measured from the time initial post-fumigation ventilation was complete and continuing through the 48 hours period. EPA has concerns about this study (see paragraph above).

II. Handlers

a. Inhalation exposures and risks to handlers: The results of the estimate of risks resulting from possible inhalation exposures to handlers (e.g., applicators and persons entering the treated greenhouse to monitor air levels or operate ventilation equipment) indicate that risks are adequately mitigated for the range of estimated air concentration levels only when a self-contained breathing apparatus is worn. This is consistent with the recommendation to EPA by the National Institute of Occupational Safety and Health (NIOSH) and the Texas Department of Health[17] (TDH) that sulfotepp fumigant labels be amended to indicate the appropriate respiratory protection" (i.e., air-supplying respirators). An analysis[18] by the California Department of Pesticide Regulation (CDPR) regarding the appropriate respiratory protection necessary for use with sulfotepp also concludes that "the only choice is self-contained breathing apparatus (SCBA). In EPA's assessment, the risks appear to be acceptable at the lower estimated air concentration level with the use of an organic-vapor-removing respirator with a high efficiency particular air (HEPA) filter. However, given the recommendations from NIOSH, TDH, and CDPR and the uncertainties in the data, including both the inhalation endpoint and the likely air concentration levels during handler activities, EPA has concluded that an air-supplied respirator is the prudent choice for all handler activities. A survey[17] of greenhouse operators in Texas conducted in 1995 by the Texas Department of Health identified 43 establishments who reported using fumigants. Of these 43 establishments, five (12 percent) indicate that handlers used respirators with an independent supply of compressed air during fumigant application. (Note: only 77 percent of the 43 establishments indicated that handlers used any respirator during fumigant application.) An internal EPA analysis[9] on the use/usage of sulfotepp found only one greenhouse operation that has self-contained breathing apparatus equipment and concluded that the cost of such equipment would be considered to be prohibitive for smaller operations.

b. Dermal exposures and risks to handlers: Though EPA did not estimate the dermal exposures and risks to handlers, the Agency has concluded that some dermal exposure, particularly to the hands and forearms, is possible. Therefore, chemical-resistant gloves should be worn by handlers in addition to the baseline attire of long-sleeve shirt, long pants, socks, and shoes.

III. Postapplication Workers

a. Inhalation exposures and risks to postapplication workers: The results of the estimate of risks resulting from possible inhalation exposure to postapplication workers (e.g., persons tending, watering, harvesting, and moving treated plants) indicate that risks appear to be acceptable at 18 days following application, but unacceptable for the range of estimated air concentration levels within 48 hours of application and *after* some ventilation has occurred. Since data indicate that sulfotepp levels fall sharply upon ventilation of the greenhouse, EPA concludes that mechanical ventilation of sufficient duration and frequency could adequately mitigate reentering workers' inhalation exposures and risks following sulfotepp applications. EPA believes that mechanical ventilation may be necessary as opposed to the generic ventilation criteria established by the Worker Protection Standard for Agricultural Pesticides (WPS) (see "d. Other considerations" below), particularly the WPS-allowed option of "24 hours with no ventilation" which may be the option of choice for growers in very cold climates. Since limited evidence indicates that sulfotepp air concentration levels rise when vents are closed again after initial ventilation, EPA concludes that 24 hours without ventilation would probably not offer sufficient reduction of air concentration levels to adequately protect reentering workers. In fact, of particular concern to EPA is the limited evidence that indicates that sulfotepp air concentration levels that fall sharply during initial ventilation of the greenhouse following application may rise again once the vents are closed or when the plants are watered. This suggests that the residues may "off-gas" over a period of time. At present, the Agency has insufficient data to determine what frequency and duration of ventilation would be necessary to sufficiently reduce risks to reentering workers in the days following application. EPA also has insufficient information to determine how long after application that inhalation exposures might be a concern, however the limited available data indicate that measurable sulfotepp levels are present at 18 days following application. In addition, since the primary use for sulfotepp is for whitefly control in mature poinsettias (e.g., November to January) in states including Michigan, New York, Ohio, and Pennsylvania, EPA is concerned that ventilation of the frequency and duration necessary to mitigate postapplication inhalation exposures in the first several days following application may not be feasible in the cold climates. EPA further notes that label instructions and other use information indicate that applications may be repeated every three days until the plants are free of pests and, therefore, inhalation exposure and risk may be even higher after the second or third application due to accumulation of sulfotepp in the greenhouse.

b. Dermal exposures and risks to postapplication workers: EPA's estimates of likely postapplication dermal exposures to reentering workers indicate that risks from short-term

exposures appear to be acceptable only for low exposure activities at approximately 38 hours following application. The intermediate-term risks remained unacceptable for low and high exposure activities through 38 hours following application, which is the longest postapplication interval for which DFR data were available. Since label instructions and other use information indicate that applications may be repeated every three days until the plants are free of pests (usually two to three applications) and the limited data indicate that measurable residues are present at 18 days following application, EPA has concluded that intermediate-term exposures to postapplication workers is likely, particularly for those uses where the plants are not shipped off site soon after application. EPA believes that a restricted-entry interval of sufficient duration could sufficiently reduce short- and intermediate-term dermal risks to postapplication workers. However, EPA is concerned about the feasibility of entry restrictions that prohibit routine entry to perform hand labor tasks for several days following application. Since one of the primary uses of sulfotepp is just before marketing to ensure the pest-free status of plants, EPA assumes routine entry to perform hand labor tasks, such harvesting and preparing plants for shipment, would be initiated as soon as possible -- at present as soon as the next morning following an evening application. Even for other uses of sulfotepp, entry of some duration would be necessitated within 24 to 48 hours following application to maintain (e.g., water, prune) the plants in greenhouse growing conditions. In any case, EPA has very limited data upon which to determine the exposure level that would sufficiently protect postapplication workers.

c. Total exposures and risks to postapplication workers: EPA's estimates of likely combined postapplication dermal and inhalation exposures to reentering workers indicate that risks from short-term and intermediate-term exposures are unacceptable through 38 hours following application, which is the longest postapplication interval for which DFR data were available. However, EPA believes that total risks would be acceptable if ventilation criteria of sufficient frequency and duration were established to mitigate inhalation risks and restrictions on entry to perform routine hand labor tasks were established at sufficient intervals (hours per day) and length (days following application) to mitigate dermal risks.

d. WPS considerations: The Worker Protection Standard for Agricultural Chemicals (WPS) establishes generic entry restrictions for fumigants applied in a greenhouse. With fumigant applications, entry is prohibited in the entire greenhouse and in any adjacent structure that cannot be sealed off from the treated area. No entry is permitted (other than entry by pesticide handlers who are trained and equipped with personal protective equipment (PPE) -- including respirators) into the greenhouse until the air concentration is measured to be equal to or less than the inhalation exposure level the labeling requires to be achieved. If an inhalation exposure level is known, it is supposed to be listed on the labeling and to serve as the controlling factor for entry. The appropriate label language for this is:

> "**AIR CONCENTRATION LEVEL**
> The acceptable air concentration level for persons exposed to sulfotepp is ?? ppm (?? mg/M^3). The air concentration level is measured by a direct reading detection device, such as a {list as appropriate: Matheson-Kitagawa, Draeger, or Sensidyne}."

Note, at this time EPA has not identified a monitoring device that detects air concentration levels for sulfotepp. EPA seeks input from the registrant about the possible existence of such a device.

When no inhalation exposure level is known (currently none is listed on the sulfotepp labeling), the WPS defaults to generic ventilation criteria. The WPS ventilation criteria include: (1) ten air exchanges are completed; (2) two hours of mechanical ventilation; (3) four hours of passive ventilation; (4) eleven hours with no ventilation followed by 1 hour of mechanical ventilation; (5) eleven hours with no ventilation followed by 2 hours of passive ventilation; or (6) twenty-four hours with no ventilation. If active-ingredient-specific ventilation criteria that differ from the default WPS ventilation criteria are established by EPA, then specific label language must be included to indicate that the WPS default criteria are being overridden.

The WPS specifies that, until any inhalation exposure level listed on the labeling is reached or, if no inhalation exposure level is listed, until one of the WPS ventilation criteria is met, *only* trained and PPE-equipped handlers are allowed into the greenhouse and even such handlers *only* are allowed into the greenhouse to operate ventilation equipment, adjust or remove coverings used in fumigation, or to monitor air levels. All other tasks are prohibited. This requirement should be specifically stated on the label. The appropriate label language for this is:

> **Greenhouse Fumigation:** Entry (including early entry that would otherwise be permitted under the WPS) by any person -- other than a correctly trained and equipped handler who is performing a handling task permitted by the WPS -- is PROHIBITED in the entire greenhouse (entire enclosed structure/building) from the start of application {{choose one of the following, as appropriate}} (1) "until aeration reduces the air concentration level of sulfotepp in the working area to less than ?? ppm" or (2) "until the greenhouse is ventilated as follows: {list ventilation criteria}}."

The WPS also requires that any handler who handles a fumigant in a greenhouse, including a handler who enters the greenhouse before the acceptable inhalation exposure level or ventilation criteria have been met to monitor air levels or to initiate ventilation, maintains continuous visual or voice contact with another handler. That other handler must have immediate access to the PPE required by the fumigant labeling for handlers in the event entry into the fumigated greenhouse becomes necessary for rescue. The appropriate label language for this is:

> "Any handler who handles this product in a greenhouse, including a handler who enters the greenhouse before the acceptable inhalation exposure level or ventilation criteria have been met to monitor air levels or to initiate ventilation, must maintain continuous visual or voice contact with another handler. That other handler must have immediate access to the PPE required on this labeling for handlers in the event entry into the fumigated greenhouse becomes necessary for rescue."

The WPS requires that the warning signs be posted at the start of application. The appropriate label language for this is:

> "NOTIFICATION: Before the start of the application, notify workers of the application by warning them orally and by posting fumigant warning signs at all entrances to the greenhouse. The signs must bear the skull and crossbones symbol and state: (1) "DANGER/PELIGRO," (2) "Greenhouse under fumigation, DO NOT ENTER/NO ENTRE," (3) the date and time of fumigation, (4) "Sulfotepp {or use brand name} Fumigant in use," and name, address, and telephone number of the applicator. Post the fumigant warning sign instead of the WPS sign for this application, but follow all WPS requirements pertaining to location, legibility, size, and timing of posting and removal.

During the implementation of the Worker Protection Standard for Agricultural Pesticides, EPA decided, based on information provided by the registrant and sketchy available data (e.g., vapor pressure), that sulfotepp should be classified as a fumigant until further data were available. The WPS defines *fumigant* as *any pesticide product that is a vapor or gas, or forms a vapor or gas on application, and whose method of pesticidal action is through the gaseous state.* Based on that interim decision, EPA assumed that applications of sulfotepp resulted in little or no dislodgeable residue on treated surfaces and, therefore, posed no dermal concern for postapplication workers. As with other fumigants, EPA's sole postapplication concern was inhalation exposures. Consequently, sulfotepp was assigned no restricted-entry interval beyond the generic prohibition on entry until any inhalation exposure level listed on the labeling was reached (sulfotepp currently has none listed) or until one of the generic WPS ventilation criteria was met. However, since data currently available to EPA indicate that sulfotepp applications do leave residues on plant surfaces that might pose a dermal concern to postapplication workers, a restricted-entry interval in hours or days should be established. Note that the WPS prohibits workers from performing routine hand labor activities, such as harvesting/cutting flowers and moving or tending plants while wearing personal protective equipment, except in emergency situations. Only handlers who are operating ventilation equipment or measuring air levels permitted entry into the greenhouse during any period where PPE is required for safe entry. In the promulgation of the WPS, EPA ruled that workers wearing PPE could not feasibly and safely perform routine hand labor tasks due to heat-stress and discomfort concerns, lack of dexterity, and poor motivation by workers being paid by productivity rather than hourly/daily wage.

III. Exposure to Others

EPA is concerned about sulfotepp fumes drifting from a treated greenhouse into attached buildings and nearby outdoor areas. According to the California Pesticide Illness Surveillance Program, three cases of poisoning occurred in 1984 when sulfotepp leaked to a work site outside the greenhouse. Another eight cases occurred in 1995 when material leaked from cracks in the greenhouse and fumes drifted 200 to 300 feet to a residential area. Current labels do not prohibit application of sulfotepp to residential greenhouses by certified applicators. There are also no current labeling restrictions about applications made in close proximity to residential or other

inhabited areas. These incidents suggest that the labeling should prohibit applications to residential greenhouses and to commercial greenhouses that are attached to structures (such as homes or buildings) where persons must be present during, or within the first few days following, the application. In addition, these incidents suggest that the Agency should consider requiring a buffer zone that prohibits sulfotepp fumigation within at least 300 feet of residential and other occupied indoor and outdoor areas.

E. HED Recommendations

Due to the uncertainties and gaps in both the toxicological and exposure databases and the low margins of exposure for sulfotepp, HED seeks further toxicity and exposure data as well as additional use information.

I. Toxicological Data:

HED notes that complete generic toxicological data on the technical grade of the active ingredient as required by the agency in 1988 and 1991 have not been submitted. Particularly necessary to this assessment are the 21-day dermal and 90- or 21-day inhalation study (HED currently believes that a 21-day inhalation study might be more appropriate).

II. Exposure Data:

HED seeks postapplication exposure monitoring studies for dislodgeable foliar residues (GL 875.21), dermal exposure (GL 875.24), and inhalation exposure (GL 875.25). Plant Products Corporation submitted a California Department of Food and Agriculture (CDFA) study[14] to the Agency in response to the generic call-in notice of October 18, 1995 and requested waivers for the postapplication dermal and inhalation exposure studies. EPA[16] reviewed the CDFA study and the waiver requests and concluded:

- the submitted CDFA study is unacceptable to fulfill the requirements of the dislodgeable foliar residue study and is not upgradeable to an acceptable study;
- the waiver request for a postapplication dermal exposure monitoring study based on the CDFA study is not acceptable; and
- the waiver request for a postapplication inhalation exposure monitoring study based on the CDFA study is not acceptable.

III. Use Information:

HED seeks further information about the use patterns associated with the use of sulfotepp smoke generators. In particular, HED would like information on a nationwide level about:

- how many greenhouses a handler may treat per day (or how many hours per day a handler may be engaged in handling activities with sulfotepp)?
- how many days per week and how many repeat applications may handlers be engaged in handling activities with sulfotepp?

- are there applications methods that could be required that would reduce the time handlers spend inside the greenhouse during application?
- are there postapplication activities (e.g., tending, watering, harvesting, shipping) that **must** be performed within a few hours or days of application? how many hours would such tasks take? how much contact with treated foliage or soil do these activities necessitate?
- in northern climates, what is the longest feasible time period that the greenhouse can be mechanically ventilated without damage to the crop?

REFERENCES

1. Plantfume 103 Smoke Generator label (EPA Reg. No. 8241-10) and Fulex Dithio Insecticide Smoke (EPA Reg. No. 1327-38).

2. U.S. EPA (1995) Sulfotepp Review of Subchronic Dog and Neurotoxicity Studies. Memo from Pamela Hurley, EPA/OPP/HED/TB to Richard King EPA/OPP/SRRD, July 13, 1995.

3. U.S. EPA (1998) Ethyl Parathion Report of the Hazard Identification Assessment Review Committee, March 25, 1998.

4. American Conference of Governmental Industrial Hygienists. (1995) 1995-1996 Threshold Limit Values (TLVs) for Chemical Substances and Physical Agents and Biological Exposure Indices (BEIs).

5. Kimmerle, G. and Klimmer, O.R. Acute and Subchronic Toxicology of Sulfotep. Arch. Toxicol. 33:1-16 (1974).

6. U.S. EPA (1998) Internal memo from John Whalen to Health Effects Division.

7. U.S. EPA (1998) Internal memo plus attachments from Jerome Blondell to Health Effects Division. "Review of Sulfotepp Incident Reports, DP Barcode D246115, Chemical #079501, Reregistration #0338."

8. BEAD Use Profile Report (02/20/97).

9. U.S. EPA (1997) Mini-analysis of the Use/Usage of the Insecticide Sulfotep. Memo from Douglas W.S. Sutherland, EPA/OPPT/HIB and Sherry Wise EPA/OPPT/EAB/BEAD to Karen Angulo EPA/OPPT/SRRD, September 5, 1997.

10. Williams, D.T.; Denley, H.V.; Lane, D.A. (1980) On site determination of sulfotepp air levels in a fumigating greenhouse. American Industrial Hygiene Association Journal 41:647-651.

12. NIOSH (1987). Guide to Industrial Respiratory Protection. National Institute for Occupational Safety and Health.

13. U.S. EPA (1997) Exposure Factors Handbook. EPA/600/P-95/002F.

14. California Department of Food and Agriculture. (1987) A study to establish degradation profiles for six pesticides (triforine, endosulfan, chlorothalonil, sulfotep, dodemorph

acetate, and daminozide) used on ornamental foliage in San Diego county California during fall 1986.

15. Williams, L.H. (1978) Dissipation of Sulfotepp and Nicotine in a Greenhouse Atmosphere Following Their Use as Fumigants. J. Environ Sci. Health B13(3):235-241.

16. U.S. EPA (1996) Internal memo from Tracy Lynn Keigwin to Health Effects Division. "OREB Review of a Foliar Dislodgeable Residue Study and Waiver Requests for Guideline Studies 875.24 and 875.25 for the Chemical Sulfotepp."

17. Morbidity and Mortality Weekly Report. (1996) Acute Pesticide Poisoning Associated with Use of a Sulfotepp Fumigant in a Greenhouse -- Texas, 1996. 45:780-782.

18. Letter dated May 1, 1998 from Dr. Dennis Gibbons in the California Department of Pesticide Regulation to Al Nielsen in U.S. EPA Health Effects Division.

POLICY STATEMENT ON THE USES OF TLVs AND BEIs

The Threshold Limit Values (TLVs®) and Biological Exposure Indices (BEIs®) are developed as guidelines to assist in the control of health hazards. These recommendations or guidelines are intended for use in the practice of industrial hygiene, to be interpreted and applied only by a person trained in this discipline. They are not developed for use as legal standards and ACGIH® does not advocate their use as such. However, it is recognized that in certain circumstances individuals or organizations may wish to make use of these recommendations or guidelines as a supplement to their occupational safety and health program. The ACGIH will not oppose their use in this manner, if the use of TLVs and BEIs in these instances will contribute to the overall improvement in worker protection. However, the user must recognize the constraints and limitations subject to their proper use and bear the responsibility for such use.

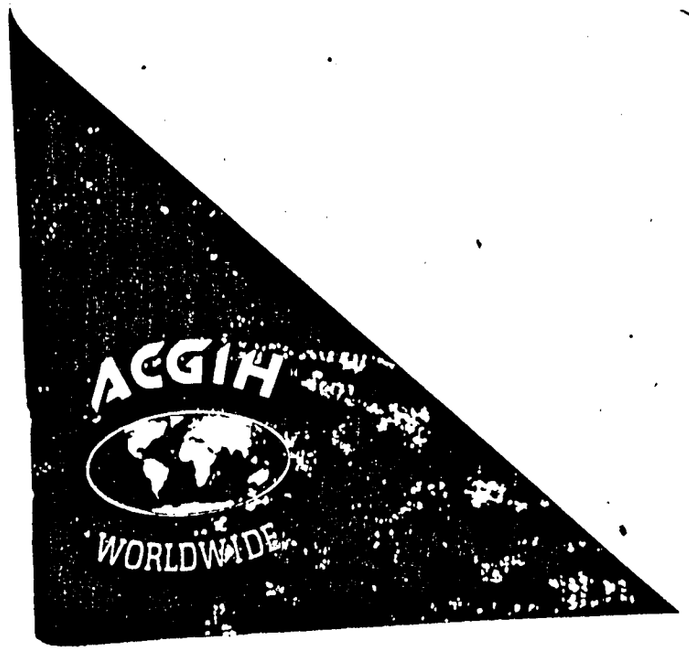
The Introductions to the TLV/BEI Booklet and the TLV/BEI Documentation provide the philosophical and practical bases for the uses and limitations of the TLVs and BEIs. To extend those uses of the TLVs and BEIs to include other applications, such as use without the judgment of an industrial hygienist, application to a different population, development of new exposure/recovery time models, or new effect endpoints, stretches the reliability and even viability of the database for the TLV or BEI as evidenced by the individual documentations.

It is not appropriate for individuals or organizations to impose on the TLVs or the BEIs their concepts of what the TLVs or BEIs should be or how they should be applied or to transfer regulatory standards requirements to the TLVs or BEIs.

The Policy Statement on the Uses of TLVs/BEIs was approved by the Board of Directors of ACGIH on March 1, 1988.

1997 TLVs® and BEIs®

Threshold Limit Values
for Chemical Substances
and Physical Agents
Biological Exposure Indices



REF. # 4

35-04-134
(35)

Substance [CAS #]	ADOPTED VALUES TWA ppm[a]	TWA mg/m³[b]	STEL/CEILING (C) ppm[a]	STEL/CEILING (C) mg/m³[b]
Starch [9005-25-8] (1996)	—	10,A4	—	—
Stearates[f] (1996)	—	10,A4	—	—
Stibine [7803-52-3] (1986)	0.1	0.51	—	—
• Stoddard solvent [8052-41-3] (1987)	100	525	—	—
Strontium chromate [7789-06-2], as Cr (1982)	—	0.0005,A2	—	—
Strychnine [57-24-9] (1986)	—	0.15	—	—
•■◀Styrene, monomer [100-42-5] (1997)	20,A4	85,A4	40,A4	170,A4
Subtilisins [1395-21-7; 9014-01-1] (Proteolytic enzymes as 100% pure crystalline enzyme) (1977)	—	—	—	C 0.00006[m]
Sucrose [57-50-1] (1996)	—	10,A4	—	—
Sulfometuron methyl [74222-97-2] (1994)	—	5,A4	—	—
◀Sulfotep [3689-24-5]—Skin (1986)	—	0.2,A4	—	—
Sulfur dioxide [7446-09-5] (1996)	2,A4	5.2,A4	5,A4	13,A4
Sulfur hexafluoride [2551-62-4] (1986)	1000	5970	—	—
Sulfuric acid [7664-93-9] (1996)	—	1,A2☆	—	3,A2☆
Sulfur monochloride [10025-67-9] (1986)	—	—	C 1	C 5.5
Sulfur pentafluoride [5714-22-7] (1986)	—	—	C 0.01	C 0.10
Sulfur tetrafluoride [7783-60-0] (1986)	—	—	C 0.1	C 0.44
Sulfuryl fluoride [2699-79-8] (1976)	5	21	10	42
Sulprofos [35400-43-2] (1986)	—	1,A4	—	—
Synthetic vitreous fibers				
•Continuous filament glass fibers (1997)	—	1 f/cc,[h]A4	—	—
•Continuous filament glass fibers (1997)	—	5,[i]A4	—	—
•Glass wool fibers (1997)	—	1 f/cc,[h]A3	—	—
•Rock wool fibers (1997)	—	1 f/cc,[h]A3	—	—
•Slag wool fibers (1997)	—	1 f/cc,[h]A3	—	—
•Special purpose glass fibers (1997)	—	1 f/cc,[h]A3	—	—
Systox, *see* Demeton				
2,4,5-T [93-76-5] (1996)	—	10,A4	—	—
Talc (containing no asbestos fibers) [14807-96-6] (1996)	—	2,[e,j]A4		

☆A2 designation refers to Sulfuric acid contained in strong inorganic acid mists.

Substance [CAS #]	ADOPTED VALUES TWA ppm[a]	TWA mg/m³[b]	STEL/CEILING (C) ppm[a]	STEL/CEILING (C) mg/m³[b]
■ Talc (containing asbestos fibers) (1985)	Use asbestos TLV–TWA[n]			
Tantalum [7440-25-7], metal and oxide [1314-61-0] dusts, as Ta (1986)	—	5	—	—
TEDP, *see* Sulfotep				
Tellurium [13494-80-9] and compounds, as Te (1977)	—	0.1	—	—
Tellurium hexafluoride [7783-80-4], as Te (1977)	0.02	0.10	—	—
◀Temephos [3383-96-8] (1986)	—	10	—	—
◀TEPP [107-49-3]—Skin (1986)	0.004	0.047	—	—
Terephthalic acid [100-21-0] (1993)	—	10	—	—
Terphenyls [26140-60-3] (1980)	—	—	C 0.53	C 5
1,1,1,2-Tetrachloro-2,2- difluoroethane [76-11-9] (1986)	500	4170	—	—
1,1,2,2-Tetrachloro-1,2- difluoroethane [76-12-0] (1986)	500	4170	—	—
‡■1,1,2,2-Tetrachloroethane [79-34-5]—Skin (1996)	1,(A4)	6.9,(A4)	—	—
Tetrachloroethylene, *see* Perchloroethylene				
Tetrachloromethane, *see* Carbon tetrachloride				
Tetrachloronaphthalene [1335-88-2] (1986)	—	2	—	—
• Tetraethyl lead [78-00-2], as Pb—Skin (1996)	—	0.1,[o]A4	—	—
Tetrahydrofuran [109-99-9] (1976)	200	590	250	737
• Tetramethyl lead [75-74-1], as Pb — Skin (1986)	—	0.15[o]	—	—
Tetramethyl succinonitrile [3333-52-6]—Skin (1986)	0.5	2.8	—	—
Tetranitromethane [509-14-8] (1996)	0.005,A3	0.04,A3	—	—
Tetrasodium pyrophosphate [7722-88-5] (1980)	—	5	—	—
Tetryl [479-45-8] (1986)	—	1.5	—	—
Thallium, elemental [7440-28-0], and soluble compounds, as Tl—Skin (1977)	—	0.1	—	—
4,4'-Thiobis(6-tert-butyl-m-cresol) [96-69-5] (1996)	—	10,A4	—	—
Thioglycolic acid [68-11-1]—Skin (1978)	1	3.8	—	—
Thionyl chloride [7719-09-7] (1986)	—	—	C 1	C 4.9
Thiram [137-26-8] (1996)	—	1,A4	—	—

While no rigorous rationale was provided for these particular values, the basic concept was intuitive: in a well-controlled process exposure, excursions should be held within some reasonable limits. Unfortunately, neither toxicology nor collective industrial hygiene experience provide a solid basis for quantifying what those limits should be. The approach here is that the maximum recommended excursion should be related to variability generally observed in actual industrial processes. In reviewing large numbers of industrial hygiene surveys conducted by the National Institute for Occupational Safety and Health, Leidel, Busch, and Crouse[1] found that short-term exposure measurements were generally lognormally distributed with geometric standard deviations mostly in the range of 1.5 to 2.0.

While a complete discussion of the theory and properties of the lognormal distribution is beyond the scope of this section, a brief description of some important terms is presented. The measure of central tendency in a lognormal description is the antilog of the mean logarithm of the sample values. The distribution is skewed, and the geometric mean is always smaller than the arithmetic mean by an amount which depends on the geometric standard deviation. In the lognormal distribution, the geometric standard deviation (sd_g) is the antilog of the standard deviation of the sample value logarithms and 68.26% of all values lie between m_g/sd_g and $m_g \times sd_g$.

If the short-term exposure values in a given situation have a geometric standard deviation of 2.0, 5% of all values will exceed 3.13 times the geometric mean. If a process displays a variability greater than this, it is not under good control and efforts should be made to restore control. This concept is the basis for the following excursion limit recommendations which apply to those TLV–TWAs that do not have STELs:

> *Excursions in worker exposure levels may exceed 3 times the TLV–TWA for no more than a total of 30 minutes during a workday, and under no circumstances should they exceed 5 times the TLV–TWA, provided that the TLV–TWA is not exceeded.*

The approach is a considerable simplification of the idea of the lognormal concentration distribution but is considered more convenient to use by the practicing industrial hygienist. If exposure excursions are maintained within the recommended limits, the geometric standard deviation of the concentration measurements will be near 2.0 and the goal of the recommendations will be accomplished.

When the toxicological data for a specific substance are available to establish a STEL, this value takes precedence over the excursion limit regardless of whether it is more or less stringent.

(1) Leidel, N.A.; Busch, K.A.; Crouse, W.E.: Exposure Measurement Action Level and Occupational Environmental Variability. DHEW (NIOSH) Pub. No. 76-131; NTIS Pub. No. PB-267-509. National Technical Information Service, Springfield, VA (December 1975).

"Skin" Notation. Listed substances followed by the designation "Skin" refer to the potential significant contribution to the overall exposure by the cutaneous route, including mucous membranes and the eyes, either by contact with vapors or, of probable greater significance, by direct skin contact with the substance. Vehicles present in solutions or mixtures can also significantly enhance potential skin absorption. It should be noted that while some materials are capable of causing irritation, dermatitis, and sensitization in workers, these properties are *not considered relevant* when assigning a skin notation. It should be noted, however, that the development of a dermatological condition can significantly affect the potential for dermal absorption.

While relatively limited quantitative data currently exist with regard to skin absorption of gases, vapors, and liquids by workers, the Chemical Substances TLV Committee recommends that the integration of data from acute dermal studies and repeated dose dermal studies in animals and/or humans, along with the ability of the chemical to be absorbed, be used in deciding on the appropriateness of the skin notation. In general, available data which suggest that the potential for absorption via the hands/forearms during the workday could be significant, especially for chemicals with lower TLVs, could justify a skin notation. From acute animal toxicity data, materials having a relatively low dermal LD_{50} (1000 mg/kg of body weight or less) would be given a skin notation. Where repeated dermal application studies have shown significant systemic effects following treatment, a skin notation would be considered. When chemicals penetrate the skin easily (higher octanol–water partition coefficients) and where extrapolations of systemic effects from other routes of exposure suggest dermal absorption may be important in the expressed toxicity, a skin notation would be considered.

Substances having a skin notation and a low TLV may present special problems for operations involving high airborne concentrations of the material, particularly under conditions where significant areas of the skin are exposed for a long period of time. Under these conditions, special precautions to significantly reduce or preclude skin contact may be required.

Biological monitoring should be considered to determine the relative contribution of exposure via the dermal route to the total dose. The TLV/BEI Booklet contains a number of adopted Biological Exposure Indices, which provide an additional tool when assessing the worker's total exposure to selected materials. For additional information, refer to "Dermal Absorption" in the "Introduction to the Biological Exposure Indices," 6th edition of the *Documentation of Threshold Limit Values and Biological Exposure Indices*, and to Leung and Paustenbach.[2]

(2) Leung, H.; Paustenbach, D.J.: Techniques for Estimating the Percutaneous Absorption of Chemicals Due to Occupational and Environmental Exposure. Appl. Occup. Environ. Hyg. 9(3):187–197 (March 1994).

Use of the skin designation is intended to alert the reader that air sampling alone is insufficient to accurately quantitate exposure and that measures to prevent significant cutaneous absorption may be required.

"Sensitizer" Notation. Listed substances followed by the designation "SEN" refer to the confirmed potential for worker sensitization as a result of dermal contact and/or inhalation exposure, based on the weight of scientific evidence. Lack of the sensitizer notation does not necessarily mean that the substance is not a sensitizer. The *Documentation of the Threshold Limit Values and Biological Exposure Indices* should be consulted for detailed information on the specific substance, the relative sensitizing potency, and whether its sensitization potential is related to dermal contact, inhalation exposure, or both.

Mixtures. Special consideration should be given also to the application of the TLVs in assessing the health hazards that may be associated with exposure to mixtures of two or more substances. A brief discussion of basic considerations involved in developing TLVs for mixtures and methods for their development, amplified by specific examples, are given in Appendix C.

Particulate Matter. For solid and liquid particulate matter, TLVs are expressed in terms of total particulate, except where the terms inhalable, thoracic, or respirable particulate are used. Refer to Endnotes. See Appendix D, Particle Size-Selective Sampling Criteria for Airborne Particulate Matter, for the definitions of inhalable, thoracic, and respirable particulate matter. The term total particulate refers to airborne material sampled with the 37mm closed face cassette traditionally used in the United States for aerosol sampling.

The intent of the Chemical Substances TLV Committee is to replace all total particulate TLVs with inhalable, thoracic, and/or respirable particulate matter TLVs. All proposed changes will be included on the Notice of Intended Changes and comments invited. Publication of the results of side-by-side sampling studies using older total and newer inhalable, thoracic, or respirable sampling techniques is encouraged to aid in the appropriate replacement of current total particulate TLVs.

Particulates Not Otherwise Classified (PNOC). There are many substances on the TLV list, and many more that are not on the list, for which there is no evidence of specific toxic effects. Those that are particulates have frequently been called "nuisance dusts." Although these materials may not cause fibrosis or systemic effects, they are not biologically inert. At high concentrations, otherwise nontoxic particulates have been associated with the occasionally fatal condition known as alveolar proteinosis. At lower concentrations, they can inhibit the clearance of toxic particulates from the lung by decreasing the mobility of the alveolar macrophages. Accordingly, the Chemical Substances TLV Committee recommends the use of the term "Particulates Not Otherwise Classified (PNOC)" to emphasize that all materials are potentially toxic and to avoid the implication that these materials are harmless at all exposure concentrations. Particulates identified under the PNOC heading are those containing no asbestos and <1% crystalline silica. To recognize the adverse effects of exposure to otherwise nontoxic particulate matter, a TLV–TWA of 10 mg/m^3 for inhalable particulate and a TLV–TWA of 3 mg/m^3 for respirable particulate have been established and are included in the adopted TLV list. Refer to the Documentation for Particulates Not Otherwise Classified (PNOC) for a complete discussion of this subject.

Simple Asphyxiants—"Inert" Gases or Vapors. A number of gases and vapors, when present in high concentrations in air, act primarily as simple asphyxiants without other significant physiologic effects. A TLV may not be recommended for each simple asphyxiant because the limiting factor is the available oxygen. The minimal oxygen content should be 18% by volume under normal atmospheric pressure (equivalent to a partial pressure, pO_2 of 135 torr). Atmospheres deficient in O_2 do not provide adequate warning and most simple asphyxiants are odorless. Several simple asphyxiants present an explosion hazard. Account should be taken of this factor in limiting the concentration of the asphyxiant.

Biological Exposure Indices (BEI). A cross reference (◀) is indicated for those substances for which there are also Biological Exposure Indices. For such substances, biological monitoring should be instituted to evaluate the total exposure, e.g., dermal, ingestion, or nonoccupational. See the BEI section in this Booklet.

Physical Factors. It is recognized that such physical factors as heat, ultraviolet and ionizing radiation, humidity, abnormal pressure (altitude), and the like may place added stress on the body so that the effects from exposure at a TLV may be altered. Most of these stresses act adversely to increase the toxic response of a substance. *Although most TLVs have built-in safety factors to guard against adverse effects to moderate deviations* from normal environments, the safety factors of most substances are not of such a magnitude as to take care of gross deviations. For example, continuous, heavy work at temperatures above 25°C WBGT, or overtime extending the workweek more than 25%, might be considered gross deviations. In such instances, judgment must be exercised in the proper adjustments of the TLVs.

Unlisted Substances. The list of TLVs is by no means a complete list of all hazardous substances or of all hazardous substances used in industry. For a large number of materials of recognized toxicity, little or no data are available that could be used to establish a TLV. Substances that do not appear on the TLV list should not be considered to be harmless or nontoxic. When unlisted substances are introduced into a workplace, the medical and scientific literature should be reviewed to identify potentially dangerous toxic effects. It may also be advisable to conduct preliminary toxicity studies. In any case, it is necessary to remain alert to adverse health effects in workers which may be associated with the use of new materials. The TLV Committee strongly encourages industrial hygienists and other occupational health professionals to bring to the Committee's attention any information which would suggest that a TLV should be established. Such information should include exposure concentrations and correlated health effects data (dose–response) that would support a recommended TLV.